

**ROSTER OF THE FDA/CDRH GENERAL AND PLASTIC SURGERY DEVICES PANEL
NOVEMBER 18, 2010**

CHAIRPERSON

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Professor of Surgery Emeritus, SUNY Downstate

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Dermatologist
Private Practice, New York, NY

A. Marilyn Leitch, M.D.
Professor of Surgery
University of Texas Southwestern Medical School, Dallas, TX

Delora L. Mount, M.D.
Associate Professor of Surgery & Pediatrics
Director of Craniofacial Anomalies Clinic & Chief of Pediatric Plastic Surgery
University of Wisconsin - Madison School of Medicine and Public Health, Madison, WI

TEMPORARY VOTING MEMBERS

Kellie J. Archer, Ph.D.¹
Associate Professor, Department of Biostatistics
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Wilma F. Bergfeld, M.D.²
Senior Dermatologist & Co-Director - Dermatopathology
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Dermatologist and Mohs Surgeon
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Retired Director, Maryland Melanoma Center
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Iris K. Rubin, M.D.
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Helen H. Wang, M.D., Dr. Ph.⁶
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PATIENT REPRESENTATIVE

Ms. Diane Aronson⁷

DESIGNATED FEDERAL OFFICER

Margaret McCabe-Janicki, B.S.
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¹ Dr. Archer is a member of, and Drs. Dodd and Zhou are consultants to, the FDA/CDRH Radiological Devices Panel.

² Drs. Bergfeld and Drake are consultants to the FDA/CDER Dermatologic & Ophthalmic Drugs Advisory Committee.

³ Dr. Connor and Ms. Stokes McElveen are members of the FDA/CDRH Gastroenterology & Urology Devices Panel (Ms. Stokes McElveen is the Consumer Representative on that Panel).

⁴ Dr. Elias is a consultant to the FDA/CDRH Immunology Devices Panel.

⁵ Dr. Hawkins is a consultant to the FDA/CDRH Chemistry & Toxicology Devices Panel.

⁶ Dr. Wang is a consultant to the FDA/CDRH Hematology & Pathology Devices Panel.

⁷ Ms. Aronson is a Consumer Representative on the FDA/CDER Arthritis Advisory Committee.

PANEL BIOGRAPHIES**Joseph LoCicero III, M.D.**

Dr. LoCicero is a General Thoracic Surgeon. He is a product of Tulane University Medical School, Tulane Surgical residency and Northwestern University Thoracic Surgery residency. His career spans three decades of clinical practice and academic medicine. He was a faculty member of Northwestern University, Harvard University, the Chicago Medical School, the University of South Alabama and SUNY Downstate. His research areas include lung transplantation, acute lung injury and thoracic malignancies. He has consulted on the development of medical devices including lung sealants, minimally invasive surgical instrumentation and chest drainage systems. He has published over 100 scientific articles and five books. He retired from active practice one year ago.

Karen E. Burke, M.D., Ph.D.

Dr. Burke is a board-certified dermatologist and research scientist with a Ph.D. (biophysics, Cornell University), post-doctoral fellowships (Cornell University Medical College and The Rockefeller University), and an M.D. (New York University Medical College). She is on the faculty of the Department of Dermatology at Mt. Sinai Medical Center where she researches antioxidants in preventing and reversing photoaging and skin cancer. Dr. Burke has written numerous research articles and medical book review chapters as well as six books for the general public (including *Thin Thighs for Life* and *Great Skin for Life*). Dr. Burke is an Honorary Life Governor of the New York Academy of Sciences and serves on the Board of Directors of the New York Stem Cell Foundation, the Parkinson's Disease Foundation, and the Women's Dermatologic Society, and is a Trustee of the Poly Prep Country Day School and an active member of the Women's Forum of the United Nations as well as of many medical and scientific organizations.

A. Marilyn Leitch, M.D.

Dr. Leitch is a Professor of Surgery at the University of Texas Southwestern Medical Center. Dr. Leitch's primary clinical interest relates to the diagnosis and treatment of breast cancer. She is considered to be a local, regional and national authority on this subject. Her other clinical interests include Ductal Carcinoma In Situ (DCIS), melanoma, sarcoma, and sentinel node biopsy.

Delora L. Mount, M.D.

Dr. Mount is Associate Professor of Surgery and Associate Professor of Pediatrics at the University of Wisconsin – Madison. She also serves as Chief of Pediatric Plastic Surgery and Director of the Craniofacial/Cleft Lip and Palate Clinic at the University of Wisconsin Hospitals and Clinics in Madison, Wisconsin. She serves on committees and boards for various professional societies and organizations, including the American Society of Maxillofacial Surgeons and the American Society of Plastic Surgeons. Dr. Mount has written numerous articles and book chapters, and has spoken nationally and internationally on a variety of subjects in her fields of expertise.

Kellie J. Archer, Ph.D.

Dr. Archer is an associate professor in the Department of Biostatistics at Virginia Commonwealth University. Her research interests include developing and applying statistical methods for analyzing high-throughput genomic data. She also has a specific interest in modeling ordinal response data for high-dimensional covariate spaces.

Wilma F. Bergfeld, M.D.

Dr. Bergfeld is Co-Director of Dermatopathology, Departments of Dermatology and Pathology and senior Staff Dermatologist and Past Head of the Section of Dermatological Research in the Department of Dermatology, Cleveland Clinic. She also is the Director of the Cleveland Clinic's Dermatopathology Fellowship and Professor of Dermatology and Pathology, The Cleveland Clinic Educational Foundation and Associate Clinical Professor, Department of Dermatology, Case Western Reserve University. Dr. Bergfeld is the author of over 600 publications, 3 books and 72 book chapters. She has served on many editorial journal boards and has been a reviewer in the both her professional fields of clinical dermatology and dermatopathology.

Scott A. Collins, M.D.

Scott Collins is in private practice in a suburb of Portland, Oregon with a practice limited to skin cancer and Mohs surgery. He is active on the state and national level in medical policy and payment issues. He serves on the AMA RUC as the American Society for Dermatologic Surgery RUC advisor. When not working, he enjoys mountain biking, fly fishing, and bird watching with his pediatrician wife Kristan.

Jason T. Connor, Ph.D.

Dr. Connor is uniquely trained as a biomedical engineer and a Bayesian biostatistician. He works at a statistical consultant designing Bayesian adaptive clinical trials for Berry Consultants. He received his PhD in Statistics & Public Policy from Carnegie Mellon University. He has coauthored over 50 papers in clinical journals. He recently finished a six-year term as an Associate Editor of The American Journal of Gastroenterology. Jason holds an Assistant Professor of Medical Education appointment at the University of Central Florida and was visiting professor at the Johns Hopkins University Bloomberg School of Public Health summer of 2010. He is a fellow of the American College of Gastroenterology.

Lynn A. Drake, M.D.

Dr. Drake is Board certified in dermatology and dermatopathology. She serves as a Lecturer in Dermatology at Harvard Medical School, and she is on staff at Massachusetts General Hospital. Dr. Drake has also served as Director of Government and Policy at Wellman Labs and Photomedicine Cutaneous Biology Research Center, which is run by Massachusetts General.

Lori E. Dodd, Ph.D.

Dr. Dodd is a mathematical statistician in the Biostatistics Research Branch of the National Institute of Allergies and Infectious Diseases. She holds a doctoral degree from the Department of Biostatistics at the University of Washington. Prior to joining NIAID, Dr. Dodd worked in the Biometric Research Branch of NCI, where she developed expertise in the evaluation of imaging in oncology trials. She has served on FDA advisory boards for the Center for Devices and Radiological Health, the RECIST committee, and other committees relating to the evaluation and the use of imaging in clinical trials. She conducts research in the areas of the statistical assessment of medical diagnostic tests and the design of clinical trials.

E. George Elias, M.D., Ph.D.

Until his retirement in 2010, Dr. Elias served as the Director of Surgical Research & Education, Department of Surgery at Franklin Square Hospital Center, and as the Director of the Maryland Melanoma Center, Weinberg Cancer Institute at Franklin Square Hospital Center in Baltimore, MD. Dr. Elias is a Fellow of the American College of Surgeons, and continues to be active in numerous professional societies and organizations in his areas of expertise. He has authored 114 scientific

Douglas M. Hawkins, Ph.D.

Douglas Hawkins is a Professor in the School of Statistics, University of Minnesota and former Chair of Applied Statistics. He is a Fellow of some of the leading professional societies in quality and statistics, and has received a number of professional awards for his research and service. His research is in applicable statistical methodology and statistical quality improvement, and has been supported by NSF, NIH and AFOSR.

Amy E. Newburger, M.D.

Dr. Newburger is founder and Director of Dermatology Consultants of Westchester, a large single specialty practice in Scarsdale, NY, Senior Attending Physician, Dept. of Dermatology at St.Luke's Roosevelt Hospital Center in NYC, and Senior Attending Physician at White Plains Hospital Medical Center in White Plains, NY. She is a former Visiting Scientist at the NCI, Expert Consultant for the Office of Professional Medical Conduct, NY State Dept. of Health, and consultant to a large consumer publication. She is a nationally recognized dermatologist who has lectured extensively to consumer, business, and medical groups across the country. She is Past President of the Westchester County Medical Society, Past President of the Westchester Academy of Medicine, Past President of the Dermatology Section of the Westchester County Medical Society, and is a former Board of Directors member of the Women's Dermatologic Society. She is a member of the American Academy of Dermatology, American Medical Association, Medical Society of the State of New York, Women's Dermatologic Society, American Society for Dermatologic Surgery, and American Contact Dermatitis Society.

Tania J. Phillips, M.D.

Dr. Phillips is an international expert in wound healing, particularly in the use of cultured skin and skin substitutes, skin aging and general dermatology. She has lectured at numerous national and international meetings and is on the editorial board of the journals *Wounds* and *Dermatologic Surgery*. Dr. Phillips is a past member of the Board of Directors of the Women's Dermatologic Society and the Association for the Advancement of Wound Care. She has co-authored three books and over 250 scientific publications.

Iris K. Rubin, M.D.

Iris Kedar Rubin, M.D. is a board-certified dermatologist in private practice in Bethesda, MD. She received her undergraduate degree with honors from Stanford University, and her medical degree from Harvard Medical School. She completed her dermatology residency training at the University of Chicago and Harvard Medical School, where she served as Academic Chief Resident. She completed a fellowship in laser surgery and cosmetic dermatology at Harvard Medical School/Wellman Center for Photomedicine.

Helen H. Wang, M.D., Dr. Ph.

Dr. Wang received her medical degree from National Taiwan University and her MPH and DrPH degrees in epidemiology and biostatistics from Harvard University. She did her residency training in anatomic pathology at Beth Israel Hospital in Boston, MA and has stayed at the same hospital since then. She is currently the director of cytopathology at Beth Israel Deaconess Medical Center and an associate professor of pathology at Harvard Medical School. She has published in various aspects of cytopathology and gastrointestinal pathology.

Dr. Zhou is Professor in the Department of Biostatistics at University of Washington and Director of Biostatistics Unit in VA Puget Sound Health Care System. Dr. Zhou is an internationally known biostatistician for his research in the area of health services research and diagnostic medicine. Dr. Zhou has published 161 referred papers in national and international journals, including 107 papers in statistical journals. In 2002, along with two co-authors, Dr. Zhou published the first textbook on statistical methods in diagnostic medicine, entitled "Statistical Methods in Diagnostic Medicine".

Michael G. Halpin

Mr. Halpin has more than twenty-two years of regulatory, quality assurance, and clinical research experience with a variety of medical device and combination product technologies. Michael has been with Genzyme for over 8 years, and currently has responsibility for the Global Regulatory Affairs function for Genzyme's orthopedic, biosurgical specialty, and cell and gene therapy products. Michael has also worked in various capacities with Abbott Laboratories, MediSense Corporation, C.R. Bard, and Abiomed, and has a background in Biomedical Engineering.

E. Francine Stokes McElveen, J.D.

Ms. Stokes McElveen serves as the Senior Advisor to the President for Legal Affairs at Coppin State University, a constituent institution of the University System of Maryland. She provides legal advice and counsel to executive officers, directors and other senior academic and administrative leaders regarding a broad range of laws, regulations, risk and policies that impact the institution. Prior to coming to Coppin State University, Ms. Stokes McElveen served as an assistant to the President of Morgan State University for government and state relations. She is also a former assistant State's Attorney for Baltimore City.

Diane Aronson

Diane Aronson serves as Consumer and Patient Representatives for the Food and Drug Administration (FDA). Working through its Center for Drug Evaluation and Research (CDER) as a Consumer Representative, Diane has served on many of its Advisory Committees and has been a standing member of the Arthritis Advisory Committee. She is a long-term survivor of malignant melanoma, having undergone radical surgery and four subsequent corrective procedures. Her experience provides a deep understanding of the challenges of addressing this devastating cancer as friends and a family member have suffered metastasizes and death from the disease.

Margaret McCabe-Janicki, B.S.

Ms. McCabe-Janicki holds a Bachelor of Science in Chemistry with a concentration in German. She has worked for FDA since 2003, first as a chemist at FDA's Center for Biologics Evaluation and Research in the Office of Vaccines Research and Review (OVRR), and then as CBER's Institutional Animal Care and Use Committee Coordinator. Margaret now serves as CDRH's Designated Federal Officer for the Gastroenterology and Urology, General and Plastic Surgery, and Hematology and Pathology Devices Panels, and for the Devices Good Manufacturing Practice (GMP) Advisory Committee.